**TITLE 345 INDIANA STATE BOARD OF ANIMAL HEALTH**

**Final Rule**
LSA Document #12-107(F)

DIGEST

Amends 345 IAC 8-2-1.7, 345 IAC 8-2-4, 345 IAC 8-2-5, 345 IAC 8-3-1, 345 IAC 8-3-2, and 345 IAC 8-3-10 to incorporate the 2011 edition of the Pasteurized Milk Ordinance and update other matters incorporated by reference and to make other changes in the law governing milk and milk products. Effective 30 days after filing with the Publisher.

**345 IAC 8-2-1.7; 345 IAC 8-2-4; 345 IAC 8-2-5; 345 IAC 8-3-1; 345 IAC 8-3-2; 345 IAC 8-3-10**

SECTION 1. 345 IAC 8-2-1.7 IS AMENDED TO READ AS FOLLOWS:

**345 IAC 8-2-1.7 "Pasteurization", "pasteurized", "ultra pasteurization", and "aseptic processing" defined**

**Authority: IC 15-17-3-21; IC 15-18-1-14**
**Affected: IC 15-17-2-82; IC 15-18-1**

Sec. 1.7. (a) As used in this article, "pasteurization" or "pasteurized" means the process of heating every particle of milk or milk product in a manner that meets all of the following requirements:

(1) The equipment is approved by the board.

(2) The equipment is properly designed and operated. Proper design and operation of the equipment under IC 15-17-2-82 and this article means design and operation according to the requirements in this section and the requirements in Section 7 Items 16p, 16p(A) through 16p(E) and Appendix H in the PMO incorporated by reference in 345 IAC 8-3-1.

(3) Each particle of milk or milk product must be heated to a temperature designated in the tables in subsection (b) and held continuously at or above that temperature for at least the time that corresponds with the temperature in the tables in subsection (b) using the type of equipment specified in the tables in subsection (b).

(b) Each of the following time and temperature requirement options is subordinate to the operating requirements prescribed in subsection (a)(2). If an operating requirement prescribes a time, temperature, and equipment combination that is different than the following table, the specific operating requirement is required:

(1) Table 1 as follows:

| Temperature | Equipment | Time |
|---|---|---|
| 63 degrees Celsius (145 degrees Fahrenheit) | vat pasteurizer | 30 minutes |
| 72 degrees Celsius (161 degrees Fahrenheit) | continuous flow pasteurizer | 15 seconds |

However, if the fat content of the milk product is ten percent (10%) or greater, the total solids content of the milk product is eighteen percent (18%) or greater, or if the milk product contains added sweeteners, the specified temperature in Table 1 shall be increased by three (3) degrees Celsius (five (5) degrees Fahrenheit).

(2) Table 2 as follows:

| Temperature | Equipment | Time |
|---|---|---|
| 89 degrees Celsius (191 degrees Fahrenheit) | continuous flow pasteurizer | 1 second |
| 90 degrees Celsius (194 degrees Fahrenheit) | continuous flow pasteurizer | 0.5 second |
| 94 degrees Celsius (201 degrees Fahrenheit) | continuous flow pasteurizer | .1 second |
| 96 degrees Celsius (204 degrees Fahrenheit) | continuous flow pasteurizer | .05 second |
| 100 degrees Celsius (212 degrees Fahrenheit) | continuous flow pasteurizer | .01 second |

(3) Notwithstanding Tables 1 and 2, eggnog shall be heated to at least the following temperature and time specifications:

| Temperature | Equipment | Time |
|---|---|---|
| 69 degrees Celsius (155 degrees Fahrenheit) | vat pasteurizer | 30 minutes |
| 80 degrees Celsius (175 degrees Fahrenheit) | continuous flow pasteurizer | 25 seconds |
| 83 degrees Celsius (180 degrees Fahrenheit) | continuous flow pasteurizer | 15 seconds |

(c) A pasteurization process that is different than those described in subsection (a) may be used if the following requirements are met:

(1) The process has been officially recognized by the United States Food and Drug Administration to be equally effective.

(2) The state veterinarian approves the procedure as being equally effective.

(d) As used in this article, "ultra pasteurized" means dairy products that have been thermally processed at or above two hundred eighty (280) degrees Fahrenheit (one hundred thirty-eight (138) degrees Celsius) for at least two (2) seconds, either before or after packaging, so as to extend the shelf life of the product under refrigerated conditions.

(e) As used in this article, "aseptic processing" **and "aseptic processing and packaging"** means the **heat processing and** filling of a ~~commercially sterilized cooled~~ **milk or milk** product into presterilized containers, followed by hermetical sealing with a presterilized closure, in an atmosphere free of microorganisms. Aseptic processing **and packaging** shall be performed in accordance with the requirements of 21 CFR **Parts 108, 110, and** 113 ~~and Section 7, Items 16p and 16p(C) and Appendix H in the Pasteurized Milk Ordinance incorporated by reference in 345 IAC 8-3~~ to maintain commercial sterility of the product under normal nonrefrigerated conditions.

**(f) As used in this article, "aseptic processing and packaging system" and "APPS" means the aseptic processing and packaging system in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade A milk or milk products. The APPS shall be constructed and operated in accordance with the applicable requirements in 21 CFR Parts 108, 110, and 113. The APPS shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the process authority may provide written documentation that clearly defines additional processes or equipment that are considered critical to the commercial sterility of the product.**

**(g) As used in this article, "low-acid aseptic milk and milk products" means milk or milk products having a water activity ($a_w$) greater than 0.85 and a finished equilibrium pH greater than 4.6 and are regulated under 21 CFR Parts 108, 110, and 113. Aseptically processed and packaged low-acid milk and milk products are stored under normal nonrefrigerated conditions. This term does not include low-acid milk and milk products that are labeled for storage under refrigerated conditions.**

*(Indiana State Board of Animal Health; 345 IAC 8-2-1.7; filed Sep 27, 2002, 2:40 p.m.: 26 IR 331; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3560; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; filed Dec 10, 2010, 10:42 a.m.: 20110105-IR-345100123FRA; filed Sep 11, 2012, 2:35 p.m.: 20121010-IR-345120107FRA)*

SECTION 2. 345 IAC 8-2-4 IS AMENDED TO READ AS FOLLOWS:

**345 IAC 8-2-4 Bulk milk collection; pickup tankers; samples**

**Authority: IC 15-17-3-21; IC 15-18-1-14**
**Affected: IC 15-18-1-12**

Sec. 4. (a) Every bulk milk pickup tanker used to collect raw milk on a bulk milk route shall be of sanitary design and construction. The owner of a tank truck shall be responsible for maintaining it and its milk contact equipment in good repair. The bulk milk pickup tanker owner is responsible for ~~making certain~~ **cleaning and sanitizing** the truck and equipment ~~have been cleaned and sanitized at least once every twenty-four (24) hours~~ **regularly** in a manner and at a location approved by the board. A cleaning and sanitizing tag approved by the board shall be completed and affixed in the rear compartment of the bulk milk pickup tanker each day after cleaning and sanitizing. The bulk milk pickup tanker and its milk contact equipment shall be protected from contamination after being cleaned and sanitized.

(b) Milk in a bulk milk pickup tanker shall be maintained at a temperature of forty-five (45) degrees Fahrenheit or less from the time of collection until delivered to a milk plant, receiving station, or transfer station. If the milk being delivered is manufacturing grade raw milk, the raw milk shall be maintained at a temperature of sixty (60) degrees Fahrenheit or less from the time of collection until delivered to a manufacturing grade milk plant, receiving station, or transfer station.

(c) Tank trucks used to transport milk shall not be used to transport other products unless they have been thoroughly washed and sanitized after having been used to transport such other products. Only products fit for human consumption are authorized to be stored or transported in tank trucks used to transport milk or milk products.

(d) The name and address of the owner of a bulk milk pickup tanker shall be legibly marked on both sides or on the rear of the vehicle. The name of the owner shall be in letters not less than three (3) inches in height provided that markings in use before March 1, 1998, may be the same height as the address, and the address shall be in letters not less than one and one-half (1 1/2) inches in height.

(e) Every bulk milk pickup tanker used to collect raw milk on a bulk milk route shall be equipped with the following:

(1) A sample dipper or other sampling device of sanitary construction approved by the board.

(2) Sampling devices protected from contamination.

(3) A sample carrying case constructed of such material and in such a way as to maintain producer raw milk samples at a temperature of thirty-two (32) to forty (40) degrees Fahrenheit from the time such samples are collected until they are delivered to the milk plant, receiving station, or transfer station.

(4) A sample rack approved by the board and of sufficient size to hold at least one (1) sample of raw milk in an upright position from each bulk milk tank of each milk producer represented on the load of raw milk being transported to a milk plant, receiving station, or transfer station, plus one (1) sample to be used for temperature determination.

(f) Each milk hauler shall be equipped with an accurate pocket-type thermometer with an unbreakable stem when collecting milk from dairy farms and shall observe the following sanitary practices in collecting milk:

(1) The hauler's hands and outer clothing shall be clean during all pickup operations.

(2) The milk shall be smelled through the port opening in the cover of the bulk tank for off-odors before raising the lid for a visual examination of the raw milk.

(3) The hauler must visually examine the raw milk in the bulk tank. Milk that is visibly unfit for human consumption in accordance with the provisions of the Uniform Indiana Food, Drug, and Cosmetic Act shall be rejected and not collected. The lid shall be closed immediately after making the visual examination whenever possible.

(4) The milk transfer hose used to withdraw raw milk from the farm bulk tank shall enter the milkhouse only through the port hole provided for that purpose.

(5) Before connecting the transfer hose to the outlet port of the farm bulk tank, the outlet port shall be sanitized. If milk has leaked past the core of the outlet valve of the farm bulk tank, the outlet port of the valve shall be washed and sanitized before withdrawing the milk.

(6) When the cap from the end of the transfer hose is being removed, it shall be handled in a sanitary manner and stored so as to prevent it from being contaminated while milk is being pumped from the farm bulk tank into the bulk milk pickup tanker.

(7) After the milk has been removed from the farm bulk tank, the bottom of the tank shall be observed for sediment and milk abnormalities.

(8) Conditions of abnormality or sediment shall be noted on the producer's copy of the weight ticket.

(9) The:

**(A)** date and time of milk collection; ~~the~~

**(B)** temperature of the raw milk; ~~and the~~

**(C) volume of milk collected;**

**(D) grade of milk collected (Grade A or manufacturing grade);**

**(E)** milk hauler's signature; and

**(F) hauler's** permit number;

shall be legibly entered on the weight ticket.

(10) After the milk has been removed from the farm bulk tank, the transfer hose shall be removed and recapped before the farm bulk tank is rinsed with water. After recapping, the transfer hose shall be rinsed free of exterior soil.

(11) A milk hauler shall not collect milk from any dairy farm for delivery to a milk plant, receiving station, or transfer station for use in Grade A milk or milk products unless the farm holds a valid permit from the board authorizing the sale of Grade A raw milk for pasteurization.

(12) At the time of collection of milk from each dairy farm, the milk hauler shall collect ~~(A)~~ only that raw milk that has been stored continuously in the farm bulk tank from the time of milking until the time of milk collection.

~~and~~ **The milk hauler shall collect one (1) of the following:**

~~(B)~~ **(A)** The entire volume of milk ~~being~~ stored in the farm bulk tank at the time of collection.

**(B) A portion of the volume of milk stored in the farm bulk tank at the time of collection may be collected only if an automatic recording chart is utilized with the tank.**

All precautions shall be taken to prevent the entrance of flies into the milkhouse.

(13) At least once each month, the milk hauler shall check the accuracy of the thermometer on each of his or her milk producer's bulk milk tanks against his or her pocket-type thermometer. The temperature obtained from both thermometers shall be entered on the weight ticket. If there is a difference between the readings on the two (2) thermometers, the reading of the bulk milk hauler's thermometer shall be reported as the official temperature on that day and on each succeeding day until the thermometer on the bulk milk tank is adjusted or repaired to be accurate.

(g) Every time a milk hauler collects milk from a dairy farm, he or she shall collect a sample of milk from each farm bulk tank **and silo** after the milk has been thoroughly agitated and before opening the outlet valve. **Samples may be collected from a properly installed and operated in-line-sampler or aseptic sampler that is approved by the board to collect representative samples.** The sample shall be collected in the following manner:

(1) If a sample dipper is used, ~~it~~ **the following apply:**

**(A) The dipper** shall be clean and transported between farms on the bulk milk route in a sanitizing solution equivalent to one hundred (100) parts per million chlorine. Other sampling devices shall be kept free of contamination.

~~(2)~~ **(B)** After removal from the sanitizing solution, all of the sanitizing solution shall be drained from the sample dipper.

~~(3)~~ **(C)** The sample dipper shall then **be:**

~~(A) be~~ **(i)** rinsed twice in the milk in the farm bulk tank; and

~~(B)~~ **(ii)** drained.

**(D) Samples must be taken through the port opening in the cover of the bulk tank.**

~~(4)~~ **(2)** A sample of not less than four (4) fluid ounces in volume or other sample sizes approved by the ~~state~~ board shall ~~then~~ be collected ~~through the port opening in the cover of the bulk tank~~ and placed in a sterile container.

~~(5)~~ **(3)** The sample container shall ~~then~~ be closed **immediately after collection** and immediately placed in melting ice water in the sample carrying case on the bulk milk pickup tanker in such a way that the top of the sample container is not submerged in the refrigerant. Producer raw milk samples shall be maintained at a temperature of thirty-two (32) to forty (40) degrees Fahrenheit until delivered to the milk plant, receiving station, or transfer station. The samples shall not be frozen.

~~(6)~~ **(4)** Each sample container shall be legibly marked with the following:

(A) The date the sample was collected.

(B) The temperature of the milk in the farm bulk tank.

(C) The route and patron number of the milk producer.

(D) In the case of Grade A milk producers, the Indiana Grade A permit number of the dairy farm from which the sample was collected.

~~(7)~~ **(5)** Before or at the time of collecting raw milk from the first milk producer on the bulk milk route, the milk hauler shall collect a sample of milk for temperature determination. The sample shall be refrigerated in the sample carrying case on the bulk milk pickup tanker until it arrives at the milk plant, receiving station, or transfer station.

~~(8)~~ **(6)** Sampling equipment shall be rinsed in clean water immediately after each usage.

~~(9)~~ **(7)** If one (1) pint samples are used to conduct sediment tests of each milk producer's raw milk, the milk hauler shall collect and legibly identify the full one (1) pint samples as requested by the milk plant, receiving station, transfer station, or board. A sample dipper of not less than one-half (1/2) pint capacity, which shall be cleaned and sanitized before the collection of each sample, shall be used. The one (1) pint samples shall be collected and transported in such a manner as to not interfere with the proper conduct of sediment tests.

(h) Bulk milk tank raw milk shall be collected within the following time frames:

(1) Manufacturing grade milk bulk tank raw milk shall be collected at least one (1) time every seventy-two (72) hours.

(2) Manufacturing grade raw milk shipped in cans shall be collected at least one (1) time every forty-eight (48) hours.

(3) Grade A bulk tank raw milk shall be collected at least one (1) time every forty-eight (48) hours.

(4) Grade A milk shipped in cans shall be collected at least one (1) time every twenty-four (24) hours.

(5) Grade A and manufacturing grade goat milk shall be collected at least one (1) time every seven (7) days.

(6) In the case of an emergency, the state veterinarian or the state veterinarian's designee may permit milk to be collected after the time frames otherwise specified in this subsection.

Bulk milk tank raw milk that is not collected within these time frames may not be collected and used for Grade A or manufacturing grade milk or milk products.

(i) It shall be the responsibility of the milk plant, receiving station, or transfer station to:
(1) provide competent personnel to receive producer raw milk samples from each bulk milk pickup tanker;
(2) ascertain and record the temperature of the temperature sample;
(3) see that the samples are properly identified and stored before delivery to the laboratory; and
(4) provide facilities for the storage of producer raw milk samples at a temperature of thirty-two (32) to forty (40) degrees Fahrenheit at which temperature they shall be maintained until they are received by an official or officially designated laboratory for analysis.

Producer raw milk samples shall not be frozen, and samples to be used for bacteriological determinations shall not be transferred to another sample container after they have been collected by the milk hauler except under conditions and by personnel approved by the board. Required laboratory analysis should begin within forty-eight (48) hours after the time of sample collection. Results of the analysis on the milk of Grade A producers shall be submitted to the board on forms and in a manner approved by the board. Milk producers and milk haulers shall not receive notice of which samples are to be used for bacteriological analysis.

(j) Any truck transporting raw, heat-treated, or pasteurized milk and milk products to a milk plant from another milk plant, receiving station, or transfer station must meet the identification and shipping requirements in IC 15-18-1-12. A shipping manifest must also indicate the bulk tank unit or units or plant identification number.

*(Indiana State Board of Animal Health; HDP 86 Rule 13, Sec 4; filed Apr 26, 1979, 12:00 p.m.: 2 IR 696, eff one hundred twenty (120) days after filing with secretary of state; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3349; errata filed Aug 13, 1998, 1:13 p.m.: 22 IR 125; errata filed Aug 13, 1998, 1:16 p.m.: 22 IR 126; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; filed Sep 27, 2002, 2:40 p.m.: 26 IR 338; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3562; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; errata filed Oct 3, 2008, 3:30 p.m.: 20081022-IR-345080767ACA; filed Sep 11, 2012, 2:35 p.m.: 20121010-IR-345120107FRA) NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-13-4) to the Indiana State Board of Animal Health (345 IAC 8-2-4) by P.L.138-1996, SECTION 76, effective July 1, 1996.*

SECTION 3. 345 IAC 8-2-5 IS AMENDED TO READ AS FOLLOWS:

**345 IAC 8-2-5 Grading raw milk and cream; testing; records**

**Authority: IC 15-17-3-21; IC 15-18-1-14**
**Affected: IC 15-18-1**

Sec. 5. (a) **The following** milk ~~or~~ **and** cream that is unfit for human consumption shall not be allowed to enter into commerce and shall be destroyed:
(1) Milk is unfit for human consumption if it meets any of the following criteria:
(A) The milk contains or shows evidence of:
**(i)** blood;
**(ii)** mastitis;
**(iii)** ropiness;
**(iv)** filth;
**(v)** insects;
**(vi)** insect parts; or
**(vii)** visible foreign matter.
(B) The milk is adulterated as defined in the Uniform Indiana Food, Drug, and Cosmetic Act.
(C) The milk contains two and seventy-five hundredths (2.75) or more milligrams weight of sediment per pint volume when sediment tested by the off-the-bottom method.
(D) The milk contains the equivalent of two and seventy-five hundredths (2.75) or more milligrams weight of sediment per gallon volume when sediment tested by the mixed sample method.
(2) Cream is unfit for human consumption if it meets any of the following criteria:
(A) The cream contains:
**(i)** filth;
**(ii)** insects;

**(iii)** insect parts; or
**(iv)** visible foreign matter.
(B) The cream has a definite wrinkled layer of white mold or significant patches of colored mold.
(C) The cream is in an active state of yeast fermentation, as evidenced by a pronounced gas or yeasty odor.
(D) The cream is:
**(i)** putrid;
**(ii)** rancid;
**(iii)** cheesy; or
**(iv)** otherwise similarly decomposed.
(E) The cream contains three (3) or more milligrams of sediment in a one (1) pint sample from cream that has been stirred.
(F) The cream is adulterated as defined in the Uniform Indiana Food, Drug, and Cosmetic Act.

(b) For ~~the~~ purposes of this rule, when a producer markets his **or her** milk through a recognized producer's marketing organization, and his **or her** milk is sent to more than one (1) milk plant, receiving station, or transfer station in any month, the management of the producer's marketing organization shall designate and inform the milk plant, receiving station, or transfer station that receives the milk when it is necessary to make the quality test required by subsections (e) through (j).

(c) Every milk plant, receiving station, or transfer station that receives raw milk or raw cream from a producer ~~of raw milk or raw cream~~ shall ~~have an approved grader of raw milk or raw cream present at all times when such products are received. The approved grader shall~~ inspect ~~and grade~~ **the** raw milk or raw cream to prevent the receiving entity from accepting raw milk or raw cream that is unfit for human consumption. The ~~grader or graders~~ **milk plant, receiving station, or transfer station** shall inspect ~~grade~~ and test all raw milk and raw cream as provided for in this rule.

(d) All sediment tests of raw milk required by this rule shall be conducted in accordance with the testing methods contained in the current edition of the standard methods; provided, the regular monthly sediment test or initial test of an individual milk producer's bulk tank raw milk may be conducted on a four (4) ounce sample of raw milk filtered through a filter disk with an exposed area of two-tenths (0.20) inch diameter. When a four (4) ounce sample is used for such a test, the same procedures as those specified for the one (1) pint raw milk mixed sample method shall be used. The method used for conducting sediment tests on milk from farm bulk tanks, tank trucks, and storage tanks shall be the mixed sample method, and the method used for conducting sediment tests of milk received in cans shall be the off-the-bottom method. Milk that is to be tested for sediment by the off-the-bottom method shall not be stirred, mixed, shaken, or handled in any unusual manner by any person or persons prior to the conduct of the sediment test. All equipment, supplies, and facilities used in the sediment testing and grading of raw milk or raw cream shall be:
**(1)** approved by the board; and ~~shall be~~
**(2)** maintained in a state of good repair.

(e) Every milk plant and receiving station that receives raw milk in cans shall conduct an off-the-bottom sediment test on the milk of each producer at least once each month. In addition, all of the milk in the first delivery from a new can milk producer shall be sediment tested. ~~If the milk is acceptable, thereafter it shall receive the monthly test hereafter described.~~

(f) If a can milk producer's milk is found to be unfit for human consumption during any test for sediment, all cans of milk in subsequent deliveries of the milk of such producer shall be sediment tested and rejected by any milk plant or receiving station until the grading of ~~such~~ **the** milk proves the milk to be fit for human consumption. In addition to this follow-up testing, the milk received from any producer of can milk who shipped milk determined to be unfit for human consumption based on the results of the regular monthly test for sediment shall be tested for sediment at least once each week thereafter until all milk in a shipment is fit for human consumption. ~~Such~~ **The** weekly tests shall be conducted on each can of milk in the **shipment or** shipments being tested.

(g) Every milk plant, receiving station, and transfer station that receives bulk tank raw milk shall conduct a mixed sample sediment test once per month of each bulk milk producer's milk that is stored in a refrigerated tank on the producer's farm. The milk hauler of the producer's milk shall collect a mixed sample of milk for sediment testing from each refrigerated farm tank and transport all ~~such~~ **the** samples to the milk plant, receiving station, or transfer station. It shall be the responsibility of the milk plant, receiving station, or transfer station that receives the

raw milk to conduct the actual sediment tests by or under the supervision of ~~an approved grader.~~ **qualified milk plant personnel.**

(h) When an individual bulk milk producer's mixed sample for sediment testing on the routine monthly or initial test establishes that the producer's milk is unfit for human consumption, subsequent offerings of milk from that farm shall be sediment tested on the farm by ~~an approved grader~~ **qualified personnel** using the one (1) pint mixed sample method prior to being mixed with the milk of any other milk producer. The producer's milk may not be accepted by any:

**(1)** milk plant;

**(2)** receiving station;

**(3)** transfer station; or

**(4)** milk hauler;

until the milk from such a farm is found to be fit for human consumption.

(i) A mixed sample of milk in the first shipment of a new bulk milk producer or a transfer bulk milk producer shall be collected by the milk hauler and transported to the milk plant, receiving station, or transfer station where it shall be tested for sediment. ~~by an approved grader. If this test shows the milk to be fit for human consumption, thereafter it shall receive the monthly test hereinbefore described.~~ However, if this test shows the milk to be unfit for human consumption, the on-the-farm follow-up testing hereinbefore described shall be done.

(j) Every milk plant, receiving station, or transfer station receiving milk from any producer shall cause a bacterial test to be conducted on a representative sample of each such producer's raw milk at least once each month. A milk hauler of producer's milk shall collect a mixed sample of milk for bacteriological testing from each refrigerated farm tank and transport all ~~such~~ **the** samples to the milk plant, receiving station, or transfer station. The kind of bacterial test employed shall be approved by the board, and the testing procedures shall be those contained in the current edition of standard methods. Each milk producer shall be notified promptly of the results of tests on his or her milk on forms and in a manner approved by the board. Records of the results of ~~such~~ **the** tests shall be kept on file for not less than one (1) year.

(k) Every milk plant, receiving station, and transfer station shall make visual and olfactory inspections of all milk and cream received. The inspections shall be made of all milk or cream immediately upon opening the original containers in which the milk or cream is received. All milk or cream found unfit for human consumption shall be rejected.

(l) Milk and cream shall be graded with respect to its sediment content by comparing the sediment tests with the official sediment standard found in the standard methods. ~~Approved graders~~ **Milk plants, receiving stations, and transfer stations** shall reject all milk and cream ~~which~~ **that:**

**(1)** does not meet the minimum standards; or ~~which~~

**(2)** is unfit for human consumption.

(m) Unfit milk or cream in cans shall be treated by the addition of a harmless red food coloring that has been certified by the U.S. Food and Drug Administration. Sufficient red coloring shall be added to such rejected products to produce a distinct red color in the milk or cream to prevent its being processed or manufactured for food. The ~~approved grader~~ **milk plant, receiving station, and transfer station** shall affix a tag of uniform type approved by the board to all containers of rejected milk or cream indicating on the tag the reason for the rejection. Under no circumstances shall such tags of rejected milk or cream be removed from a container holding rejected milk or cream except by the producer of ~~such~~ **the** rejected milk or cream.

(n) ~~Approved graders~~ **Qualified milk plant personnel** shall identify rejected milk in farm bulk tanks or in bulk milk transportation tank trucks by affixing a tag of uniform type approved by the board to the tank in which the milk is located. The reason for the rejection of the milk shall be stated on the tag. Rejected milk shall not be transported by anyone to a location for manufacture or processing into food. The rejection tag shall remain on the bulk farm tank or bulk milk transportation tank truck until the unfit product has been dumped to waste or removed for salvage for use other than for food.

(o) On the next shipment following a rejection of a producer's milk, a milk plant, receiving station, or transfer station shall not receive more milk (reasonable variations in milk volume being permitted) from that producer than

the producer normally ships per delivery.

(p) Every milk plant, receiving station, and transfer station shall keep or cause to be kept a complete system of records, including monthly records of quality tests, all other tests, pickups, and deliveries. Records relating to milk and cream shall be kept by **the:**

(1) ~~the~~ route, name, number, or other identification of the producer;
(2) ~~the~~ date of the test;
(3) ~~the~~ nature of the test;
(4) ~~the~~ classification of the test;
(5) ~~the~~ total producers tested;
(6) ~~the~~ number of producers of milk or cream rejected; and
(7) ~~the~~ number of cans and estimated pounds of milk or cream of each producer rejected.

A summary of results of all tests made during the current month shall be mailed to the board not later than the fifteenth day of the following month on forms prescribed and furnished by the board.

(q) Sediment tests on samples of bulk milk shall be conducted as follows:

(1) Thoroughly agitate the milk in the bulk tank for at least five (5) minutes before collecting samples to be tested.
(2) Heat the milk sample to a temperature of ninety (90) to one hundred (100) degrees Fahrenheit before conducting the sediment test.
(3) Shake the milk sample thoroughly, immediately before conducting the sediment test.
(4) Use a bulk milk sediment tester to filter milk to be tested through a standard cotton lintine disk or equivalent sediment filtering material. The bulk milk sediment tester that may be either pressure or vacuum operated must be designed so that it will not permit the milk being tested to bypass the filter disk or filtering material.
(5) If all of the milk sample will not filter through the sediment disk, use additional disks until all the milk in the sample has been filtered.
(6) Remove the sediment disk from the tester and place it in a white sediment card with a transparent opening.
(7) Grade sediment disks by comparing them with a raw milk bulk tank mixed sample sediment standard in the standard methods.

*(Indiana State Board of Animal Health; HDP 86 Rule 13, Sec 5; filed Apr 26, 1979, 12:00 p.m.: 2 IR 698, eff one hundred twenty (120) days after filing with secretary of state; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3352; errata filed Aug 13, 1998, 1:16 p.m.: 22 IR 126; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; filed Sep 11, 2012, 2:35 p.m.: 20121010-IR-345120107FRA) NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-13-5) to the Indiana State Board of Animal Health (345 IAC 8-2-5) by P.L.138-1996, SECTION 76, effective July 1, 1996.*

SECTION 4. 345 IAC 8-3-1 IS AMENDED TO READ AS FOLLOWS:

**345 IAC 8-3-1 Incorporation by reference; standards**

**Authority: IC 15-17-3-19; IC 15-17-3-21; IC 15-18-1-14**
**Affected: IC 15-17-2; IC 15-18-1**

Sec. 1. (a) The board incorporates by reference as a rule of the board the Grade A Pasteurized Milk Ordinance, United States Department of Health and Human Services, Public Health Service, Food and Drug Administration ~~(2009~~ **(2011** revision), referred to as the PMO for regulation of the production, transportation, processing, handling, sampling, examination, grading, labeling, and sale of all Grade A milk and milk products in the state. Except where specifically excluded, the board intends to incorporate all parts of the PMO to include all of the administrative procedures and the appendixes. However, the following parts of the PMO are not incorporated by reference as a rule of the board:

(1) Section 16 on penalties.
(2) Section 17 on repeal and date of effect.
~~(3) Appendix K.~~
~~(4)~~ **(3)** Appendix P.

The board intends to incorporate the footnoted language in the PMO regarding cottage cheese that will apply to any person producing Grade A cottage cheese and Grade A dry curd cottage cheese. However, a person may produce cottage cheese and dry curd cottage cheese as a manufacturing grade milk product (not Grade A) by

complying with the manufacturing grade milk products requirements under this article. ~~(b)~~ References in the PMO to the regulatory agency shall mean and refer to the board.

**(b) The board will utilize the latest edition of the following documents when interpreting and implementing the provisions of the PMO, this article, and IC 15-18:**

**(1) The following National Conference on Interstate Milk Shipments model documents:**

**(i) Procedures Governing the Cooperative State-Public Health Service / Food and Drug Administration Program of the National Conference on Interstate Shipments.**

**(ii) Methods of Making Sanitation Ratings of Milk Shippers.**

**(iii) Evaluation of Milk Laboratories.**

**(2) The following sets of documents issued by the United States Food and Drug Administration, Milk Safety Branch:**

**(i) Memoranda of Interpretation (M-a series documents).**

**(ii) Memoranda of Milk Ordinance Equipment Compliance (M-b series documents).**

**(iii) Memoranda of Information (M-I series documents).**

(c) The board adopts by reference the general provisions relating to food standards set forth by the United States Food and Drug Administration in 21 CFR 130.8, 21 CFR 130.9, 21 CFR 130.10, and 21 CFR 130.11, in effect on April 1, ~~2009.~~ **2012.**

(d) The board adopts by reference the definitions and standards of identity for milk and milk products set forth by the United States Food and Drug Administration in 21 CFR 131.3 et seq., titled "Part 131–Milk and Cream", in effect on April 1, ~~2009.~~ **2012.** Milk and milk products must conform to these standards.

(e) The board adopts by reference the definitions and standards of identity for cheeses and related cheese products set forth by the United States Food and Drug Administration in 21 CFR 133.3 et seq., titled "Part 133–Cheeses and Related Cheese Products", in effect on April 1, ~~2009.~~ **2012.** Cheese and cheese products must conform to these standards.

(f) The board adopts by reference the definitions and standards of identity for frozen desserts set forth by the United States Food and Drug Administration in 21 CFR 135.3 et seq., titled "Part 135-Frozen Desserts", in effect on April 1, ~~2009.~~ **2012.** Frozen desserts must conform to these standards.

(g) The board adopts by reference the current good manufacturing practices for manufacturing, packing, or holding human food set forth by the United States Food and Drug Administration in 21 CFR 110 and 21 CFR 113, in effect on April 1, ~~2009.~~ **2012.** The criteria and definitions in 21 CFR 110, 21 CFR 113 and this rule shall apply in determining whether a food is adulterated under IC 15-18-1 in that the food has been manufactured under such conditions that it is unfit for human food or the food has been prepared, packed, or held under unsanitary conditions under which the product may:

(1) become contaminated with filth; or

(2) have been made injurious to health.

(h) The board adopts by reference as a rule of the board the food labeling requirements set forth by the United States Food and Drug Administration in 21 CFR 101, but not including Subpart C, in effect on June 1, ~~2009.~~ **2012.**

(i) The board incorporates by reference into this rule the definitions set forth in IC 15-17-2 and the matters set forth in IC 15-18-1.

(j) Where the matters incorporated by reference in this section conflict with provisions of this article, IC 15-17-2, or IC 15-18-1, the express provisions of this article and the Indiana Code shall control.

(k) Incorporated documents are available for public inspection at the board. **Copies of incorporated documents and interpreting and implementing documents may be obtained from the Food and Drug Administration, Milk Safety Branch website, the U.S. Government Printing Office website, or by sending a written request to the board.**

*(Indiana State Board of Animal Health; 345 IAC 8-3-1; emergency rule filed Jan 27, 1994, 5:00 p.m.: 17 IR 1223,*

*eff Feb 1, 1994; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3354; errata filed Aug 13, 1998, 1:16 p.m.: 22 IR 126; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; filed Sep 27, 2002, 2:40 p.m.: 26 IR 340; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3564; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; filed Dec 18, 2007, 3:45 p.m.: 20080116-IR-345070296FRA; filed Aug 11, 2008, 3:37 p.m.: 20080910-IR-345080125FRA; errata filed Oct 3, 2008, 3:30 p.m.: 20081022-IR-345080767ACA; filed Dec 10, 2010, 10:42 a.m.: 20110105-IR-345100123FRA; filed Sep 11, 2012, 2:35 p.m.: 20121010-IR-345120107FRA) NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-14-8.1) to the Indiana State Board of Animal Health (345 IAC 8-3-1) by P.L.138-1996, SECTION 76, effective July 1, 1996.*

SECTION 5. 345 IAC 8-3-2 IS AMENDED TO READ AS FOLLOWS:

**345 IAC 8-3-2 Grade A milk production and storage**

**Authority: IC 15-17-3-21; IC 15-18-1-14**
**Affected: IC 15-18-1-18**

Sec. 2. The following are required to hold a Grade A dairy farm permit:
(1) Milk that is produced or processed must meet the chemical, bacteriological, and temperature standards in Section 7 and Table 1 of the PMO adopted by reference in section 1 of this rule.
(2) The farm must meet the sanitation, construction, operation, and other standards in the provisions of the Pasteurized Milk Ordinance adopted by reference in section 1 of this rule, including the following:
(A) Section 7, "Standards for Grade "A" Raw Milk For Pasteurization, Ultra-Pasteurization, or Aseptic Processing **and Packaging",** Items 1r through 19r.
(B) Appendix C, "Dairy Farm Construction Standards; Milk Production".
(C) Appendix D, "Standards for Water Sources".
(D) Appendix F, "Sanitization".
(E) A farm utilizing an automatic milking installation (AMI) must comply with Appendix Q.
(3) The animals on the farm must meet the animal health requirements in IC 15-18-1-18 and Section 8 of the Pasteurized Milk Ordinance adopted by reference in section 1 of this rule.
(4) The "administrative procedures" set forth in the Pasteurized Milk Ordinance adopted by reference in section 1 of this rule shall be followed in implementing the standards required in this section.
(5) Before:
(A) milkhouses;
(B) milking barns;
(C) stables; or
(D) parlors;
regulated under this rule are constructed or extensively altered, construction plans shall be submitted to the state veterinarian for written approval before work is begun.
(6) Raw milk for pasteurization shall not be stored:
(A) on a dairy farm for more than forty-eight (48) hours; and
(B) outside a farm bulk milk tank.
(7) Agitation and refrigeration of all farm bulk milk cooling and holding tanks shall be automatically controlled with automatic controls that will maintain mixed milk temperature between thirty-two (32) degrees Fahrenheit and forty-five (45) degrees Fahrenheit and an interval timer that will activate agitation of the milk for a minimum period of two (2) minutes in every sixty (60) minute interval. ~~Persons holding Grade A permits issued under this article on January 1, 2003, must meet the automatic refrigeration and interval timer requirements in this subsection not later than January 1, 2005. All plans for new construction or extensive alteration that are submitted for approval under this section, however, shall meet the refrigeration and interval timer requirements in this subsection. All applicants for a new Grade A permit shall meet the refrigeration and interval timer requirements of this subsection as a condition of receiving the permit.~~

*(Indiana State Board of Animal Health; 345 IAC 8-3-2; emergency rule filed Jan 27, 1994, 5:00 p.m.: 17 IR 1224, eff Feb 1, 1994; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3355; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; filed Sep 27, 2002, 2:40 p.m.: 26 IR 341; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3565; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; errata filed Oct 3, 2008, 3:30 p.m.: 20081022-IR-345080767ACA; filed Sep 11, 2012, 2:35 p.m.: 20121010-IR-345120107FRA) NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-14-8.2) to the Indiana State Board of Animal Health (345 IAC 8-3-2) by P.L.138-1996, SECTION 76, effective July 1, 1996.*

SECTION 6. 345 IAC 8-3-10 IS AMENDED TO READ AS FOLLOWS:

**345 IAC 8-3-10 Grade A milk plants standards**

**Authority: IC 15-17-3-21; IC 15-18-1-14**
**Affected: IC 15-18-1**

Sec. 10. A person operating a Grade A milk plant shall meet the following requirements:
(1) Milk that is processed must meet the chemical, bacteriological, and temperature standards in Section 7 and Table 1 of the Pasteurized Milk Ordinance adopted by reference in section 1 of this rule. Milk from manufacturing grade dairy farms may not be used.
(2) The milk plant must meet the sanitation, construction, operation, and other standards set forth in the Pasteurized Milk Ordinance adopted by reference in section 1 of this rule, including the following:
(A) Section 6, "The Examination of Milk and Milk Products".
(B) Section 7, "Standards for Grade "A" Pasteurized, Ultra-Pasteurized and Aseptically Processed **and Packaged** Milk and Milk Products", Items 1p through ~~19p.~~ **22p.**
(C) The personnel health standards and procedures set forth in Sections 13 and 14.
(D) Appendix D, "Standards for Water Sources".
(E) Appendix F, "Sanitization".
(F) Appendix G, "Chemical and Bacteriological Tests".
(G) Appendix H, "Pasteurization Equipment and Procedures".
(H) Appendix I, "Pasteurization Equipment and Controls–Tests".
(I) If a plant fabricates containers, Appendix J, "Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products".
(J) Appendix N, "Drug Residue Testing and Farm Surveillance".
(K) Appendix O, "Vitamin Fortification of Fluid Milk Products".
**(L) A milk plant that enters into an agreement with the board to participate in a voluntary HACCP Program under Appendix K shall comply with the requirements of the agreement and Appendix K.**
(3) Milk for pasteurization, ultra-pasteurization, or aseptic processing **and packaging** may be obtained only from dairy farms that hold a valid Grade A dairy farm permit issued under this article or, in the case of milk from outside the state, is a source that is listed on the National Conference of Interstate Milk Shipments interstate milk shippers list as meeting standards equal to or greater than the Grade A standards in the Pasteurized Milk Ordinance incorporated by reference in section 1 of this rule.
(4) The "administrative procedures" set forth in the Pasteurized Milk Ordinance adopted by reference in section 1 of this rule shall be used in implementing the standards required in this section.

*(Indiana State Board of Animal Health; 345 IAC 8-3-10; filed Sep 27, 2002, 2:40 p.m.: 26 IR 341; errata, 26 IR 793; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; filed Sep 11, 2012, 2:35 p.m.: 20121010-IR-345120107FRA) NOTE: Agency cited as 345 IAC 8-3-3, which was renumbered by the publisher as 345 IAC 8-3-10.*

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